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510(k) Summary

Split Cath® III
Summary of Safety and Effectiveness
Prepared June 10, 2011

Section 5
General Information

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 Phone: (215) 256-4201 Fax: (215) 256-9191
Contact:	Jean Callow Regulatory Specialist
Device Trade Name:	Split Cath® III
Common Name:	Hemodialysis Catheter, Implanted
Classification Name:	MSD – Blood access device and accessories
CFR Reference:	21 CFG 876.5540, Class III
Classification Panel:	Gastroenterology / Urology

Predicate Devices:

Device Trade Name:	Split Cath® II
Common Name:	Hemodialysis Catheter, Implanted
Classification Name:	MSD –Blood access device and accessories
CFR Reference:	21 CFR 876.5540, Class III
Classification Panel:	Gastroenterology / Urology
Premarket Notification:	K040318, concurrence date February 3, 2011 K020465, concurrence date July 22, 2002 K091953, concurrence date September 16, 2009 K051280, concurrence date November 30, 2005 K981125, concurrence date February 26, 1999

Performance Standards: Performance standards have not been established by FDA under section 514 of the Federal Food, Drug, and Cosmetic Act.

Indications for Use:

The Medcomp® Split Cath® III is indicated for use in attaining long term vascular access for Hemodialysis and Apheresis.

It may be inserted percutaneously and is primarily placed in the internal jugular vein.

Alternate insertion sites include the subclavian vein.

Catheters greater than 40cm are intended for femoral vein insertion.

Indications for Use: (translumbar placement)

The Medcomp® Split Cath® III is indicated for use in attaining long term vascular access for Hemodialysis and Apheresis in the adult patient.

It may be inserted percutaneously and is primarily placed in the internal jugular vein.

Alternate insertion sites include the subclavian vein and inferior vena cava as required.

Catheters greater than 40cm are intended for femoral vein or inferior vena cava insertion.

Translumbar insertion via inferior vena cava is indicated when all other access sites are identified as non-viable.

Device Description:

- 14 French, double "D" lumen design with cuff for long-term implant.
- Variety of lumen lengths from 20cm to 55cm.
- Soft radiopaque polyurethane material
- Lumen is connected to the extension via a soft pliable hub with a suture wing
- Red and blue clamps and red and blue sleeves are provided on the extension tube to prevent air/fluid communications
- The hub contains the device name and French size, clamp I.D. Rings are printed with the priming volume.

Safety and Performance Tests

Biocompatibility requirements of ISO 10993 *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing* for externally communicating, blood contacting, long-term devices were met. All materials used in the manufacture of the Split Cath® III were previously cleared for similar applications by Medcomp, Inc.

Performance testing of the Split Cath® III was conducted in accordance with the following international standards:

- *ISO 10555-1: 1997, Sterile Single Use-Intravascular Catheters, General Requirements*
- *ISO 10555-3: 1997, Sterile Single Use-Intravascular Catheters, Central Venous Catheters*
- *ISO 594-2: Conical Fittings with a 6% (Luer) Taper for Syringes, Needles, and Certain Other Medical Equipment – Part 2: Lock Fittings*

Subject product testing has yielded acceptable safety and performance outcomes.

The results of these tests, in conjunction with the substantial equivalence claims effectively demonstrate that the Split Cath® III is substantially equivalent to the cited predicate devices.

Testing performed:
Air Leakage
Liquid Leakage
Priming Volume
Flow verse Pressure
Force at Break / Tensile Strength

Recirculation
Chemical Exposure
Accelerated Aging

Summary of Substantial Equivalence

Based on the indications for use and safety and performance testing, the Split Cath® III meets the requirements that are considered for its intended use and is substantially equivalent in design materials, sterilization, and indications for use to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC - 8 2011

Ms. Jean Callow
Regulatory Specialist
Medcomp
1499 Delp Drive
HARLEYSVILLE PA 19438

Re: K111651
Trade/Device Name: Medcomp® Split Cath® III
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: November 23, 2011
Received: November 28, 2011

Dear Ms. Callow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

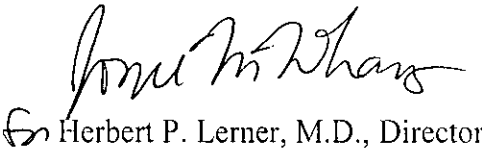
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known): K111651

Device Name: Medcomp® Split Cath® III (translumbar insertion)

Indications for Use:

The Medcomp® Split Cath® III is indicated for use in attaining long term vascular access for Hemodialysis and Apheresis in the adult patient.

It may be inserted percutaneously and is primarily placed in the internal jugular vein.

Alternate insertion sites include the subclavian vein and inferior vena cava as required.

Catheters greater than 40cm are intended for femoral vein or inferior vena cava insertion.

Translumbar insertion via inferior vena cava is indicated when all other access sites are identified as non-viable.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111651

Indications for Use

510(k) Number (if known): K111651

Device Name: Medcomp® Split Cath® III

Indications for Use:

The Medcomp® Split Cath® III is indicated for use in attaining long term vascular access for Hemodialysis and Apheresis.

It may be inserted percutaneously and is primarily placed in the internal jugular vein.

Alternate insertion sites include the subclavian vein.

Catheters greater than 40cm are intended for femoral vein insertion.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111651